Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Assesing the Effect of problem solving skill based intervention on Stress, Anxiety and Depression associated with infertility in Infertile couples

Protocol summary

Study aim
Determining the effect of intervention based on problem-solving skills on stress, anxiety and depression associated with infertility on infertility couples between two group and inside each of them ,before and after intervention

Design
A clinical control trial with two intervention and control groups, based on problem-solving skills, is randomized[gs

Settings and conduct
counseling sessions will be held at Urmia Shahid Motahari Hospital

Participants/Inclusion and exclusion criteria
Infertile couples who have high grade of stress and anxiety and can attend counseling sessions They are between 18 and 40 so far they have no children and they have no physical or mental illness

Intervention groups
The intervention includes five sessions)every is 90 min) the first two sessions are for general information about infertility and problem-solving skills run for all participants together, and the other three sessions will be run on problem-based issues like as couple counseling The control group will also undergo a routine infertility treatment process

Main outcome variables
scores of stress , anxiety and depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151004024340N14**
Registration date: **2018-09-19, 1397/06/28**
Registration timing: **retrospective**
Last update: **2018-09-19, 1397/06/28**
Update count: **0**

Registration date
2018-09-19, 1397/06/28

Registrant information

Name
Hamideh Mohaddesi

Name of organization / entity
Urmia University of Medical Science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-05, 1397/02/15

Expected recruitment end date
2018-09-06, 1397/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assesing the Effect of problem solving skill based intervention on Stress, Anxiety and Depression associated with infertility in Infertile couples

Public title
the Effect of problem solving skill based intervention on Stress, Anxiety and Depression associated with infertility in Infertile couples

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Resident of urmia Ages 18 to 40Minimum elementary education Primary infertility The first couple visit for the infertility treatment Earning a score below 28 from the GHQ-28 questionnaire Earn a minimum score of milder and higher grades based on the DASS questionnaire sub-scales Having no child The possibility of spouse joining in meetings notice about the infertility factor Being a single wife Not having a medical condition Non-use of narcotic's drug, and alcohol The absence of a history or current condition for mental problems No severe stressful incident occurred during the last 6 months, except for the diagnosis of infertility Having a mobile phone

Exclusion criteria:

Age over 40 years Secondary infertility Residents of cities other than Urmia Illiteracy History of mental illness

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done in a simple way. Our randomized units were paired in this study the randomization method was using sealed envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran (Postal Code:571478334)

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-03-07, 1396/12/16

Ethics committee reference number

IR.UMSU.REC .438

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

inability to achieve a pregnancy, sterility

Primary outcomes

1

Description

stress questionnaire

Timepoint

Before intervention and 1 month after intervention

Method of measurement

Depression ,Anxiety and Stress 42 (DASS42) Questionnaire

2

Description

Anxiety

Timepoint

Before start the intervention and 1 month after finished the intervention

Method of measurement

Depression , Anxiety and Stress 42 (DASS42) Questionnaire

3

Description

Depression DASS-42 questionnaire

Timepoint

Before start the intervention and 1 month after finished the intervention

Method of measurement

Depression , Anxiety and Stress 42 (DASS42) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The intervention includes five sessions)every is 90 min) the first two sessions are for general information about infertility and problem-solving skills run for all participants together, and the other three sessions will be run on problem-based issues like as couple counseling .First session :introduction , presentation of information about infertility, explanation of cognitive-behavioral counseling and discussion of positive and negative thoughts, A.B.C training. Teaching conflict management techniques and challenging inefficient thoughts.second Session: Complete problem solving skills training and multiple practice exercises with couples and provide a checklist as a homework assignment.third Session: Diagnostic interviews and identification of beliefs and types of coping ways of couples specificly against problems.Fourth Session: Teaching Mindfulness Techniques to Improve Couple's Consciousness in Addressing the Issues Fifth Session : summarizing and reviewing the contents of the sessions.

Category
Behavior

2

Description
Control group: recieve the routiine treatment

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Motahhari hospital of Urmia

Full name of responsible person
Mahsa Hasanzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Mahsa Hasanzadeh

Position
Master's student in midwifery counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Publishing research results in the form of article publishing

When the data will become available and for how long
Start the access period 6 monthsafter printing the results

To whom data/document is available
public

Under which criteria data/document could be used
Consultation and support program in health centers

From where data/document is obtainable
Hamideh Mohaddesi Contact umber00989143413242 E-mail: Mohaddesi.han@gmail.ccom

What processes are involved for a request to access data/document
Login to Urmia University of Medical Sciences and search for thesis

Comments